

Mark R. Elam, Chairman Jim P. Creel, Jr., Vice-Chairman Charles M. Joye, II, P.E., Secretary J.B. (Sonny) Kinney

Seema Shrivastava-Patel Richard V. Lee, Jr. Morris E. Brown, III, MD, FAAFP Robert R. Morgan, Jr., MD, MBA

#### Minutes of the May 13, 2021, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, May 13, 2021, at 11:00 a.m. in the Boardroom (#3420) at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina.

The following members were in attendance:

Mark Elam, Chairman Seema Shrivastava-Patel, 2<sup>nd</sup> District Richard V. Lee, Jr., 5<sup>th</sup> District Robert Morgan, M. D., 4th District Morris E. Brown III, M. D., 6th District

In attendance virtually: J. B. (Sonny) Kinney, 1st District Charles M. Joye, II, P. E., 3<sup>rd</sup> District Jim P. Creel, 7th District

Also, in attendance were Dr. Edward Simmer, Director, W. Marshall Taylor, Jr., General Counsel, Department staff, and members of the public. The meeting was also available via Livestream.

Chairman Elam called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

#### Item 1: Minutes of April 8, 2021 meeting

Mr. Lee moved, seconded by Dr. Morgan, to approve the minutes as presented. The Board voted and the motion carried.

#### **Item 2: Agency Affairs:**

Dr. Edward Simmer, Director, updated the Board on:

- staffing temporary and permanent positions and the agency's return to in-person attendance:
- leadership training;
- Dr. Brannon Traxler move from Interim Director of Public Health Director to the permanent role;

- filling the agency's leadership positions in Legislative Affairs and Chief of Staff;
- COVID-19 testing and vaccination updates;
- DHEC and EPA efforts regarding the New Indy Paper Facility;
- hurricane preparation;
- Environmental Justice Program and efforts with North Charleston flooding;
- Healthcare Quality has withdrawn amendments to the midwife regulations; and
- Tracking COVID-19 visitation in long term care facilities.

After discussion, the Board accepted this item as information.

After discussion, Dr. Morgan moved, seconded by Mr. Lee, for the Board to go into Executive Session for legal advice related to long term care facility visitation reporting. The Board voted and the motion carried.

### Item 3: Administrative and Consent Orders issued by Healthcare Quality

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, two (2) Consent orders with assessed Civil Penalties totaling \$1,885, thirty-nine (39) Notices of Violation and Civil Penalties totaling \$13,350, in assessed civil penalties, and (1) Administrative Order was issued.

After discussion, the Board accepted this item as information.

### Item 4: Administrative and Consent Orders issued by Environmental Affairs

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period twenty-seven (27) Consent Orders with assessed civil penalties totaling \$55,310 and eighteen (18) Administrative Orders with assessed civil penalties totaling \$25,630 were issued.

After discussion, the Board accepted this item as information.

# Item 5: Request for Removal of Samidorphan from Schedule II for Controlled Substances in South Carolina

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, presented this item to the Board.

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a final rule to remove samidorphan (3-carboxamido-4-hydroxy naltrexone) and its salts from the schedules of the Controlled Substances Act ("CSA"). The Department recommends removing this substance from Schedule II in the same manner as the federal Drug Enforcement Administration.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the removal of samidorphan (3-carboxamido4-hydroxy naltrexone) and its salts, from Schedule II for controlled substances in South Carolina and the amendment of Section 44-53-210(B)(1) of the South Carolina Controlled Substances Act.

After discussion, Mr. Lee moved, seconded by Ms. Shrivastava-Patel, to remove Samidorphan and the additional substances named in the DEA Notice published in the Federal Register on April 19, 2021 and amend Section 44-53-210(B) of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.

# Item 6: Request Placement of Ten Specific Fentanyl-Related Substances in Schedule I for Controlled Substances in South Carolina

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, presented this item to the Board.

On April 27, 2021, the Drug Enforcement Administration ("DEA") published a final rule which placed 10 specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. This final rule imposes permanent controls on 10 specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Substances Act ("CSA"). These 10 fentanyl-related substances are: N-(1-(2-fluorophenethyl)piperidin4-yl)-N-(2-fluorophenyl)propionamide (2'-fluoro ortho-fluorofentanyl; 2'-fluoro 2-fluorofentanyl); N-(1-(4-methylphenethyl)piperidin4-yl)-N-phenylacetamide (4'-methyl acetyl fentanyl); N-(1phenethylpiperidin-4-yl)-N,3- diphenylpropanamide (β'-phenyl fentanvl: Phenyl fentanyl; 3- phenylpropanoyl fentanyl); N-phenyl-N-(1-(2- phenylpropyl)piperidin-4- yl)propionamide (β-methyl fentanyl); N-(2-fluorophenyl)-N-(1- phenethylpiperidin-4yl)butyramide (ortho-fluorobutyryl fentanyl); N-(2-methylphenyl)-Nphenethylpiperidin-4-yl)acetamide (ortho-methyl acetyl fentanyl; methylacetyl fentanyl); 2-methoxy-N-(2-methylphenyl)-N-(1-phenethylpiperidin-4yl)acetamide (ortho-methyl methoxyacetylfentanyl); N-(4methylphenyl)-N-(1phenethylpiperidin-4-yl)propionamide (para-methylfentanyl; 4- methylfentanyl); N-(1-phenethylpiperidin-4-yl)-N-phenylbenzamide (phenyl benzoyl fentanyl); and N-(1-phenethylpiperidin-4-yl)-Nphenylthiophene-2-carboxamide (thiofuranyl fentanyl; 2-thiofuranyl fentanyl; thiophene fentanyl). The schedule I listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing these 10-specific fentanyl-related substances in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing of these 10 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act.

After discussion, Dr. Morgan moved, seconded by Mr. Lee to designate the ten specific fentanyl-related substances named in the DEA Notice published in the Federal Register on April 27, 2021, and amend Section 44-53-190(B) of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.

## <u>Item 7: Request Placement of Four Specific Fentanyl-Related Substances in Schedule</u> <u>I for Controlled Substances in South Carolina</u>

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, presented this item to the Board.

On May 4, 2021, the Drug Enforcement Administration ("DEA") published a final rule which placed four specified fentanyl-related substances permanently in schedule I of the Controlled Substances Act. This final rule imposes permanent controls on four specified fentanyl-related substances, which will continue to be listed in schedule I of the Controlled Act These 4 fentanyl-related ("CSA"). substances phenethylpiperidin-4-yl)(phenyl)carbamate (fentanyl carbamate); N-(2-fluorophenyl)-N-(1phenethylpiperidin-4-yl)acrylamide (orthofluoroacryl fentanyl); N-(2-fluorophenyl)-N-(1phenethylpiperidin-4-yl)isobutyramide (orthofluoroisobutyryl fentanyl); and N-(4fluorophenyl)-N-(1-phenethylpiperidin-4-yl)furan-2-carboxamide (parafluoro furanyl fentanyl). The schedule I listing of these four fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing these 4-specific fentanyl-related substances in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing of these 4 fentanyl-related substances includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act.

After discussion, Mr. Lee moved, seconded by Ms. Shrivastava-Patel to designate the four specific fentanyl-related substances named in the DEA Notice published in the Federal Register on May 4, 2021, and amend Section 44-53-190(B) of the S.C. Controlled Substances Act for consistency with the Federal scheduling. After discussion, the Board voted and the motion carried.

# <u>Item 8: Request for Placement of Serdexmethylphenidate in Schedule IV for Controlled Substances in South Carolina</u>

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, presented this item to the Board.

On March 2, 2021, the United States Food and Drug Administration ("FDA") approved a new drug application for AZSTARYS capsules for oral use, a combination drug product containing serdexmethylphenidate chloride and dexmethylphenidate hydrochloride, for the treatment of Attention Deficit Hyperactivity Disorder in patients six years of age or older. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place serdexmethylphenidate and its salts in schedule IV of the Controlled Substances Act ("CSA").

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of serdexmethylphenidate, including its salts, isomers, and salts of isomers, in Schedule IV for controlled substances in South Carolina and the amendment of Section 44-53-250 of the South Carolina Code of Laws.

After discussion Dr. Morgan moved, seconded by Ms. Shrivastava-Patel, to designate Serdexmethylphenidate and the additional substances named in the DEA Notice published in the Federal Register on March 2, 2021, and amend Section 44-53-250 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.

# Item 9: Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-63, Radioactive Materials (Title A), Document No. 5036, Exempt from General Assembly Review

A Public Hearing was conducted concerning the Regulation. Mr. Russell Morrison presented this item to the Board.

Healthcare Quality proposes the attached Notice of Final Regulation amending R.61-63, Radioactive Materials (Title A), for publication in the May 28, 2021, South Carolina State Register ("State Register"). Legal authority resides in S.C. Code Section 13-7-40, which designates the Department as the responsible agency for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as they are for compliance with federal law as required to maintain South Carolina's federal compatibility with the United States Nuclear Regulatory Commission ("NRC") as an Agreement State. The amendments will take legal effect as of the May 28, 2021, publication in the State Register.

After discussion, Mr. Lee moved, seconded by Dr. Brown, that based on the public hearing and documents herein, to find for the need and reasonableness of the Proposed Amendment of Regulation 61-63, Radioactive Materials (Title A), Document No. 5036, and grant approval to publish the attached Notice of Final Regulation for legal effect as of the May 28, 2021, publication in the State Register. The Board voted and the motion carried.

A verbatim transcript of these proceedings is included as part of the official record.

Item 10: Final Review Conference - Docket No. 21-RFR-27, Ridgeview Community Care Homes, Inc. - CRC-0559, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Angie Smith presented this item to the Board. Julie Cox presented this item to the Board on behalf of Ridgeview Community Care Homes, Inc.

Item 11: Final Review Conference - Docket No. 21-RFR-28, Ridgeview Community Care Homes, Inc. - CRC-0560, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Angie Smith presented this item to the Board. Julie Cox presented this item to the Board on behalf of Ridgeview Community Care Homes, Inc.

Item 12: Final Review Conference - Docket No. 21-RFR-29, Ridgeview Community Care Homes, Inc. - CRC-0561, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Angie Smith presented this item to the Board. Julie Cox presented this item to the Board on behalf of Ridgeview Community Care Homes, Inc.

Item 13: Final Review Conference - Docket No. 21-RFR-30, Ridgeview Community Care Homes, Inc. - CRC-0562, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021

Ms. Angie Smith presented this item to the Board. Julie Cox presented this item to the Board on behalf of Ridgeview Community Care Homes, Inc.

Mr. Sonny Kinney moved, seconded by Mr. Lee, to consolidate agenda items 10-13, as they concern the same facility and matter. The Board voted and the motion carried.

After discussion, Dr. Simmer suggested partially upholding the staff decision and collect a total of \$350 from Ridgeview Community Care Homes, Inc., If there were no further violations within four (4) weeks, the fine would be remitted back to Ridgeview Community Care Homes, Inc.

After discussion, Mr. Lee moved, seconded by Ms. Shrivastava-Patel to revise the staff decision to incorporate the suggestions made by Dr. Simmer. The Board voted and the motion carried.

Mr. Lee spoke to the Board about the following issues related to COVID-19:

contact tracing;

- vaccination waivers and current guidelines for schools;
- class size guidelines;
- large gathering guidelines;
- reviewing cleaning guidelines in schools;
- Mr. Lee thanked the ACC for coordinating the vaccination clinic in York County.

Being no further business, Chairman Elam adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,

Sharles M. Joye, II, PE

Minutes approved this 10th of June, 2021.

ATTEST:

Mark R. Elam, Chairman

#### Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Minutes of April 8, 2021 meeting
- 3-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 4-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 5-1 Request for Removal of Samidorphan from Schedule II for Controlled Substances in South Carolina
- 6-1 Request Placement of Ten Specific Fentanyl-Related Substances in Schedule I for Controlled Substances in South Carolina
- 7-1 Request Placement of Four Specific Fentanyl-Related Substances in Schedule I for Controlled Substances in South Carolina
- 8-1 Request for Placement of Serdexmethylphenidate in Schedule IV for Controlled Substances in South Carolina
- 9-1 Public Hearing and Request for Final Approval, Proposed Amendment of Regulation 61-63, *Radioactive Materials (Title A)*, Document No. 5036, Exempt from General Assembly Review
- 9-2 Public Hearing Sign Up Sheet
- 9-3 Verbatim transcript of public hearing
- 10-1 Final Review Conference Docket No. 21-RFR-27, Ridgeview Community Care Homes, Inc. CRC-0559, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021
- 11-1 Final Review Conference Docket No. 21-RFR-28, Ridgeview Community Care Homes, Inc. - CRC-0560, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021
- 12-1 Final Review Conference Docket No. 21-RFR-29, Ridgeview Community Care Homes, Inc. – CRC-0561, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021
- 13-1 Final Review Conference Docket No. 21-RFR-30, Ridgeview Community Care Homes, Inc. CRC-0562, Issuance of Notice of Violation and Civil Penalty for violation of Public Health Order No. COVID-19-5 by failing to submit a weekly report by the 5:00 PM deadline of Monday, March 8, 2021